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STENT FABRICATION METHOD

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FIELD OF THE INVENTION

The present invention relates generally to methods of fabricating stents.

BACKGROUND OF THE INVENTION

15 Stents are known in the art. They are typically formed of a cylindrical metal mesh which can expand when pressure is internally applied. Alternatively, they can be formed of wire wrapped into a cylindrical shape.

20 As described in U.S. 4,776,337 to Palmaz, the cylindrical metal mesh shape is produced by laser cutting a thin walled metal tube. The laser cuts away all but the lines and curves of the mesh.

25 The method of U.S. '337 is applicable for relatively large mesh shapes and for meshes whose lines are relatively wide. However, for more delicate and/or intricate shapes, the spot size of the laser is too large.

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SUMMARY OF THE PRESENT INVENTION

It is, therefore, an object of the present invention to provide a stent fabrication method which can produce stents with relatively intricate and/or delicate designs.

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The method involves first creating a flat version of the desired stent pattern from a piece of thin sheet metal. The flat pattern can be produced through any suitable technique, such as etching the design into the sheet metal, or by cutting with a very fine laser, should one become commercially available or by any other technique.

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Once the sheet metal has been cut, it is deformed so as to cause its edges to meet. To create a cylindrical stent from a flat, roughly rectangular metal pattern, the flat metal is rolled until the edges meet. The locations where edges meet are joined together, such as by spot welding. Afterwards, the stent is polished, either mechanically or electrochemically.

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It is an object of this invention to provide an apparatus for fabricating a stent, comprising:

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a) a platform adapted to receive a flat sheet of metal to be formed into the stent, the flat sheet of metal having a longitudinal axis, a first major surface, a second major surface, a first long side, and a second long side, the first and the second long sides substantially parallel to the longitudinal axis of the sheet;

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b) a mandrel having a substantially cylindrical external surface and having a first end and a second end defining a

5 longitudinal axis, the mandrel sized to have a cross-sectional diameter substantially equal to or less than the internal diameter of the stent to be fabricated;

c) means for securing the mandrel against a major surface of the flat sheet of metal; and

10 d) means for deforming the flat sheet of metal against the external surface of the mandrel so that the flat sheet of metal is deformed into a substantially tubular shape, the means for deforming adapted so that the first long side and the second long side remain substantially parallel to each other when the flat
15 sheet of metal is deformed into the tubular shape.

It is another object of this invention to provide and apparatus for fabricating a stent, comprising:

a) a base having a platform adapted to receive a flat sheet of metal to be formed into the stent, the flat sheet of
20 metal having a longitudinal axis, a first major surface, a second major surface, a first long side, and a second long side, the first and the second long sides substantially parallel to the longitudinal axis of the stent;

b) a mandrel having a substantially cylindrical external
25 surface and having a first end and a second end defining a longitudinal axis, the mandrel sized to have a cross-sectional diameter substantially equal to or less than the internal diameter of the stent to be fabricated;

c) means for securing the mandrel against a major surface
30 of the flat sheet of metal;

5 d) a plurality of deforming blades disposed around the
periphery of the mandrel for deforming the flat sheet of metal
against the external surface of the mandrel so that the flat
sheet of metal is deformed into a substantially tubular shape,
the blades disposed between the first end and the second end of
10 the mandrel, each of the deforming blades adapted for independent
and selective movement in a first direction toward the mandrel
and a second direction away from the mandrel so as to selectively
impinge upon the mandrel or upon a portion of the sheet disposed
between the mandrel and each of the deforming blades, each of the
15 deforming blades further adapted so that the first long side and
the second long side of the sheet remain substantially parallel
to each other when the stent is deformed into the tubular shape;

 e) means for selectively moving each of the deforming
blades in a first direction toward the mandrel and in a second
20 direction away from the mandrel; and

 f) means for securing the first long side of the sheet to
the second long side of the sheet.

It is yet another object of this invention to provide
an apparatus for fabricating a stent, comprising:

25 means for securing the first long side of the sheet to the second
long side of the sheet.

It is still another object of this invention to provide
an apparatus for fabricating a stent, comprising:

a) a base;

30 b) a sheet receiving area disposed on the base, the area

5 adapted to receive a flat sheet of metal to be formed into the stent, the flat sheet of metal having a longitudinal axis, a first major surface, a second major surface, a first long side, and a second long side, the first and the second long sides substantially parallel to the longitudinal axis;

10 c) an arm having a first end and a second end, the first end of the arm adapted to selectively retain a mandrel having a substantially cylindrical external surface, the second end of the arm hingedly connected to the base and adapted for movement in a first direction toward the base and in a second direction away from the base and further adapted to secure the mandrel against a major surface of the flat sheet of metal disposed on the stent receiving area disposed on the base, the mandrel sized to have a cross-sectional diameter substantially equal to or less than the internal cross-sectional diameter of the stent to be fabricated;

15 d) means for deforming the flat piece of metal against the external surface of the mandrel so that the flat sheet of metal is deformed into a substantially tubular shape substantially conforming to the external surface of the mandrel with the first long side and the second long side substantially parallel to each other.

20 It is yet another object of this invention to provide a stent aligning and welding jig comprising:

25 a) a base having a first end and a second end, a first wall having a first end and a second end and a first major surface and a second major surface; a second wall having a first

5 end and a second end and a first major surface and a second major
surface, the second major surface of the first wall and the first
major surface of the second wall defining a longitudinal U-shaped
channel having a longitudinal axis in the base, the first wall
provided with a plurality of slots defining a plurality of first
10 clamping portions having a top end and a bottom end and a first
major surface and a second major surface, each of the first
clamping portions provided with a first concave channel disposed
at the top end of the second major surface of the first clamping
portion and a second concave channel disposed at the bottom end
15 of the second major surface of the first clamping portion, the
first and the second concave channels substantially parallel to
the longitudinal axis of the U-shaped channel; the first wall of
each of the plurality of first clamping portions provided with a
compensation slit disposed between the first concave channel and
20 the second concave channel, the compensation slit substantially
parallel to the longitudinal axis of the U-shaped channel;

 b) a plurality of second clamping portions disposed in the
U-shaped channel between the second major surface of the first
wall and the first major surface of the second wall, each of the
25 second clamping portions disposed in registry with one of the
first clamping portions, each of the second clamping portions
having a top end, a bottom end, a first major surface, a second
major surface, a first minor surface disposed at the top end, a
second minor surface disposed at the bottom end, a third minor
30 surface disposed between the top end and the bottom end, and a

5 fourth minor surface disposed opposite the third minor surface
between the top end and the bottom end, each of the second
clamping portions provided with a first concave channel disposed
at the top end of the first major surface of the second clamping
portion and a second concave channel disposed at the bottom end
10 of the first major surface of the second clamping portion, the
first and the second concave channels substantially parallel to
the longitudinal axis of the U-shaped channel;

 c) a biasing means disposed between the first major
surface of the second wall and the second major surface of each
15 of the plurality of second clamping portions for biasing the
first major surface of each of the second clamping portions
against the second major surface of each of the first clamping
portions which are in registry with each other;

 d) a first mandrel support lever positioning pin
20 projecting from the third minor surface and a second mandrel
support lever positioning pin projecting from the fourth minor
surface of each of the second clamping portions, the mandrel
support lever positioning pins substantially parallel to the
longitudinal axis of the U-shaped channel;

25 e) a biasing control means for selectively controlling the
distance between the second major surface of each of the first
clamping portions and the first major surface of each of the
second clamping portions;

 f) a retaining mandrel disposed in the second concave
30 channel of the first wall and the second concave channel in each

5 of the second clamping portions; and

g) a mandrel support lever for supporting the stent during the alignment of the first long side of the sheet with the second long side of the sheet, the lever provided with a first mandrel support notch for supporting the first end of the mandrel, a
10 second mandrel support notch for supporting the second end of the mandrel, a first mandrel support lever positioning pin engagement surface for engaging the first mandrel support lever positioning pin and a second mandrel support lever positioning pin engagement surface for engaging the second mandrel support lever positioning
15 pin when the mandrel support lever is disposed on the second wall.

It is still another object of this invention to provide a method of fabricating a stent comprising the steps of:

a) providing a plurality of stent patterns into a
20 flat piece of metal, each of the patterns having a first long side and a second long side, the first long side provided with a plurality of pairs of engagement points, the second long side provided with a plurality of pairs of engagement points, the plurality of pairs of engagement points disposed substantially
25 opposite each other, the engagement points sized and disposed to communicate when the pattern is deformed and rolled into a tubular shape, each pair of the first long side engagement points provided with a bridge disposed between each first long side engagement point comprising the pair, the bridge having a width
30 that is less than the width of the other portions of the stent;

5 b) disposing a mandrel having a substantially cylindrical external surface and a longitudinal axis between the first long side and the second long side of the sheet, the longitudinal axis substantially parallel to the first long side and the second long side;

10 c) deforming the pattern into a tubular shape so that the first long side pairs of engagement points contact the second long side pairs of engagement points;

 d) cutting the bridge; and

15 e) attaching each of the engagement points to the engagement point with which it is in contact to form the expandable stent.

 It is yet another object of this invention to provide a jig for electropolishing a tubular stent, comprising:

 a) a base;

20 b) an electrically conductive first member having a first end connected to the base and a second end adapted to selectively contact the external surface of the tubular stent without damaging the external surface;

25 c) an electrically non-conductive second member having a first end connected to the base and a second end adapted to be selectively disposed within the longitudinal bore of the stent without damaging the longitudinal bore, the first member and the second member further adapted so as to bias the second end of the second member towards the second end of the first member in an
30 amount sufficient to secure the stent between the first and the

5 second members.

It is still another object to this invention to provide a method of electropolishing a stent, comprising the steps of:

10 a) mounting a stent on a rack, the rack having a first end and a second end provided with a plurality of stent electropolishing mounts, each of the mounts having a base; an electrically conductive first member having a first end connected to the base and a second end adapted to selectively contact the external surface of the tubular stent without damaging the external surface; an electrically non-conductive second member
15 having a first end connected to the base and a second end adapted to be selectively disposed within the longitudinal bore of the stent without damaging the longitudinal bore, the first member and the second member further adapted so as to bias the second end of the second member towards the second end of the first
20 member in an amount sufficient to secure the stent between the first and the second members;

b) immersing the stent in an electropolishing bath and applying electrical current to the first member for a predetermined period of time; and

25 c) changing the point where the second end of the first member contacts the external surface of the stent prior to the expiration of the predetermined period of time.

It is yet another object of this invention to provide a method of fabricating a stent comprising the steps of:

30 a) providing a plurality of stent patterns in a flat

5 sheet of metal; each of the patterns having a first long side and
a second long side, the first long side provided with a plurality
of pairs of engagement points, the second long side provided with
a plurality of pairs of engagement points, the plurality of pairs
of engagement points disposed substantially opposite each other,
10 the engagement points sized and disposed to communicate when the
pattern is deformed and rolled into a tubular shape, each pair of
the first long side engagement points provided with a bridge
disposed between each first long side engagement point comprising
the pair, the bridge having a width that is less than the width
15 of the other portions of the stent;

b) disposing a mandrel having a substantially
cylindrical external surface and a longitudinal axis between the
first long side and the second long side of the sheet, the
longitudinal axis substantially parallel to the first and the
20 second long sides;

c) deforming the pattern into a tubular shape so that
the first long side pairs of engagement points contact the second
long side pairs of engagement points and allowing a portion of
the stent to remain attached to the sheet of metal;

25 d) cutting the bridge;

e) attaching each of the engagement points to the
engagement point with which it is in contact to form the stent;

f) attaching an electrode to the sheet of metal;

g) electropolishing the stent; and

30 f) disconnecting the stent from the sheet.

5 It is yet another object of this invention to provide a sheet for fabricating a stent having a longitudinal lumen:

 a) a flat piece of sheet metal provided with a plurality of stent patterns, each of the patterns having a first long side and a second long side, the first long side provided
10 with a plurality of pairs of engagement points, the second long side provided with a plurality of pairs of engagement points, the plurality of pairs of engagement points disposed substantially opposite each other, the engagement points sized and disposed to communicate when the pattern is deformed and rolled into a
15 tubular shape, each pair of the first long side engagement points provided with a bridge disposed between each first long side engagement point comprising the pair, the bridge having a width that is less than the width of the other portions of the stent.

 It is yet another object of this invention to provide a
20 method for fabricating a stent having a longitudinal lumen comprising the steps of:

a.) constructing an apparatus comprising:

 a) a laser housing;
 b) a laser disposed within and selectively movable within
25 the housing;
 c) a movable table having a first end and a second end and adapted for selective movement into and out of the laser housing the table adapted so that when the first end of the table is disposed within the laser housing the second end of the table is
30 disposed outside of the housing and when the second end of the

5 table is disposed within the laser housing the first end of the
table is disposed outside of the laser housing;

d) a plurality of stent folders disposed at the first end
of the table and a plurality of stent folders disposed at the
second end of the table, each of the stent folders comprising:

10 a) a base having a platform adapted to receive a flat
sheet of metal to be formed into the stent, the flat sheet
of metal having a longitudinal axis, a first major surface,
a second major surface, a first long side, and a second long
side, the first and the second long sides substantially
15 parallel to the longitudinal axis, the sheet provided with a
plurality of alignment of apertures;

b) a plurality of alignment pins projecting from each
of the platforms, the pins sized to engage the alignment
apertures and align the sheet on the platform;

20 c) a mandrel having a substantially cylindrical
external surface and having a first end, a second end, and a
longitudinal axis, the mandrel sized to have a cross-
sectional diameter substantially equal to or less than the
internal diameter of the stent to be fabricated, the
25 platform provided with a first concave recess adapted to
receive the first end of the mandrel and a second concave
recess adapted to receive the second end of the mandrel;

30 d) a hingedly connected arm adapted for movement in a
first direction toward the platform and in a second
direction away from the platform for securing the mandrel

5 against a major surface of the flat sheet of metal;

 e) a first deforming blade provided with a first
deforming blade tip; a second deforming blade provided with
a second deforming blade tip; a third deforming blade
provided with a third deforming blade tip; a fourth
10 deforming blade provided with a fourth deforming blade tip;
a fifth deforming blade provided with a fifth deforming
blade tip; and a sixth deforming blade provided with a sixth
deforming blade tip, the blades disposed around the external
surface of the mandrel, the deforming blade tips adapted to
15 deform the flat sheet of metal against the external surface
of the mandrel so that the flat sheet of metal is deformed
into a substantially tubular shape substantially conforming
to the external surface, the deforming blades disposed
between the first end and the second end of the mandrel,
20 each of the deforming blades adapted for independent and
selective movement in a first direction toward the mandrel
and a second direction away from the mandrel so as to
selectively impinge the deforming blade tips against the
mandrel or against a portion of the sheet disposed between
25 the mandrel and each of the deforming blade tips, each of
the deforming blades further adapted so that the first long
side and the second long side of the sheet remain
substantially parallel to each other when the stent is
deformed into the tubular shape, the third and the sixth
30 deforming blade tips provided with a plurality of scalloped

5 laser apertures, the apertures sized and disposed to permit
the third and the sixth deforming blade tips to secure the
first long side and the second long side against the
external surface of the mandrel while providing the laser
access to predetermined portions of the first long side and
10 the second long side of the sheet in order to weld the first
long side to the second long side;

f) a first motor connected to the first deforming
blade; a second motor connected to the second deforming
blade; a third motor connected to the third deforming blade;
15 a fourth motor connected to the fourth deforming blade; a
fifth motor connected to the fifth deforming blade; and a
sixth motor connected to the sixth deforming blade, each of
the motors adapted for selectively moving each of the
deforming blades to which it is connected in a first
20 direction toward the mandrel and in a second direction away
from the mandrel; and

g) a computer for controlling: the sequence which the
first end of the table and the second end of the table are
disposed within the laser housing; for controlling the
25 sequence and degree to which each of the plurality of
deforming blade tips impinges upon the mandrel or a portion
of the sheet disposed between the mandrel and each of the
deforming blade tips; and for controlling the sequence,
pattern, location, and amount of energy the laser applies to
30 each of the first and the second long sides of each of the

5 sheets disposed on each of the plurality of stent folders;

b.) cutting a plurality of stent patterns into a flat piece of metal, each of the patterns having a first major surface and a second major surface, a first long side and a second long side, 10 the first long side provided with a plurality of pairs of engagement points, the second long side provided with a plurality of pairs of engagement points, the plurality of pairs of engagement points disposed substantially opposite each other, the engagement points sized and disposed to communicate when the 15 pattern is deformed and rolled into a tubular shape, each pair of the first long side engagement points provided with a bridge disposed between each first long side engagement point comprising the pair, the bridge having a width that is less than the width of the other portions of the stent, the sheet provided with a 20 plurality of alignment apertures sized and disposed to engage the alignment pins on the base;

c.) disposing the sheet on the base so that the first major surface of the sheet is in contact with the base;

d.) disposing a mandrel having a substantially cylindrical 25 external surface and a longitudinal axis against the second major surface of the sheet between the first long side and the second long side of the sheet, the longitudinal axis substantially parallel to the first long side and the second long side;

e.) deforming the pattern into a tubular shape so that the first 30 long side pairs of engagement points contact the second long side

5 pairs of engagement points the deforming step comprising the steps of:

a) actuating the sixth deforming blade motor so that the sixth deforming blade motor moves the sixth deforming blade in the first direction in an amount
10 sufficient for the sixth deforming blade tip to contact the external surface of the mandrel so as to secure the mandrel against the sheet;

b) actuating the first deforming blade motor so that the first blade deforming motor moves the first
15 deforming blade in the first direction in an amount sufficient for the first blade deforming tip to contact the first major surface of the sheet and deform the sheet against the external surface of the mandrel;

c) actuating the second deforming blade motor so that
20 the second deforming blade motor moves the second deforming blade in the first direction in an amount sufficient for the second deforming blade tip to contact the first major surface of the sheet and deform the sheet against the external surface of the mandrel;

d) actuating the third deforming blade motor so that
25 the third deforming blade motor moves the second deforming blade in the first direction in an amount sufficient for the third deforming blade tip to contact the first major surface of the sheet and deform the
30 sheet against the external surface of the mandrel while

5 actuating the sixth deforming blade motor so that the
 sixth deforming blade moves in the second direction
 away from the mandrel;

10 e) actuating the fourth deforming blade motor so that
 the fourth deforming blade motor moves the fourth
 deforming blade tip in the first direction in an amount
 sufficient for the fourth deforming blade tip to
 contact the first major surface of the sheet and deform
 the sheet against the external surface of the mandrel;

15 f) actuating the fifth deforming blade motor so that
 the fifth deforming blade motor moves the fifth
 deforming blade in the first direction in an amount
 sufficient for the fifth deforming blade tip to contact
 the first major surface of the sheet and deform the
 sheet against the external surface of the mandrel;

20 g) actuating the sixth deforming blade motor so that
 the sixth deforming blade motor moves the second
 deforming blade in the first direction in an amount
 sufficient for the second deforming blade tip to
 contact the first major surface of the sheet and deform
 the sheet against the external surface of the mandrel;

25 h) simultaneously actuating the third and sixth
 deforming blade motors so that the third and sixth
 deforming blade motors move the third and sixth
 deforming blades in the first direction in an amount
 sufficient for the third and sixth deforming blade tips

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5 to contact the first major surface of the sheet and
 deform the sheet against the external surface of the
 mandrel;

 d) utilizing the laser in cutting the bridge; and

 e) utilizing the laser in welding each of the engagement points
10 to the engagement point with which it is in contact to form the
 expandable stent.

 It is a further object of this invention to provide a stent
having a longitudinal lumen, comprising: a first long side and a
second long side, the first long side provided with a plurality
15 of pairs of engagement points, the second long side provided with
a plurality of pairs of engagement points, the plurality of pairs
of first long side engagement points and the plurality of pairs
of second long side engagement points disposed substantially
opposite each other and connected to each other via a weld, the
20 weld wider than the other portions of the stent.

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BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the drawings in which:

Fig. 1 is a flow chart illustration of the stent
10 fabrication method of the present invention;

Figs. 2A, 2B and 2C are illustrations of three alternative stent patterns to be etched, in accordance with the method of Fig. 1, into a flat sheet of metal;

Fig. 3 is an isometric illustration of a stent being
15 deformed, useful in understanding the method of Fig. 1;

Fig. 4 is an isometric illustration of a stent formed from the method of Fig. 1;

Figs. 5A and 5B are side and top view illustrations, respectively, of one connection location of the stent of Fig. 4;

20 Fig. 6 is a side view illustration of one connection location of the stent of Fig. 4 which is connected in a nail-like manner;

Fig. 7 shows a piece of sheet metal with a plurality of patterns made in accordance with the invention;

25 Fig. 8 shows a detailed view of one of the patterns shown in Fig. 7;

Fig. 9 shows a detailed view of a pair of engagement troughs shown in Fig. 8;

30 Fig. 10 shows a detailed view of a pair of engaging protrusions shown in Fig. 8;

5 Fig. 11 shows the engagement troughs and engagement protrusions of Figs. 9 and 10 in the engaged position;

 Fig. 12 shows a welding run practiced in accordance with the invention;

10 Fig. 13 is a detailed view of the welding run shown in Fig. 12;

 Fig. 14 is a detailed view of a cell of a stent made in accordance with this invention;

 Fig. 15 is a detailed view of a cell made in accordance with this invention;

15 Fig. 16 shows a cell of a stent made in accordance with this invention;

 Fig. 17 is an enlarged view of the cell shown in Fig. 16;

20 Fig. 18 is a cross-sectional view of a longitudinal member of a stent constructed in accordance with this invention;

 Fig. 19 is a cross-sectional view of a stent constructed in accordance with this invention;

 Fig. 20 is a perspective view of a stent constructed in accordance with this invention;

25 Fig. 21 is a cross-sectional front view of an unexpanded stent made in accordance with the invention;

 Fig. 22 is a cross-sectional front view of the stent shown in Fig. 21 after it has been expanded;

30 Fig. 23 is a cross-sectional front view of an unexpanded stent made by cutting a pattern in a tube; and

5 Fig. 24 is a cross-sectional front view of the stent shown in Fig. 23 after expansion;

 Fig. 25 shows an apparatus for constructing a stent made in accordance with the invention;

 Fig. 26 shows an apparatus for constructing a stent
10 made in accordance with the invention;

 Fig. 27 is an enlarged view of a portion of the apparatus shown in FIG. 26;

 Fig. 28 shows engagement points constructed in accordance with the invention;

15 Fig. 29 show engagement points constructed in accordance with the invention;

 Fig. 30A to 30I shows the sequence of making a stent using the apparatus of FIGS. 25 and 26;

 Fig. 31 shows details of a v-shaped notch and gap
20 formed in accordance with the invention;

 Fig. 32 shows details of two blade deforming tips made in accordance with the invention;

 Fig. 33 shows an alternative embodiment of engagement of engagement points constructed in accordance with the
25 invention;

 Fig. 34 shows an alternative embodiment of engagement points constructed in accordance with the invention;

 Fig. 35 shows a mandrel utilized in accordance with the invention;

30 Fig. 36 shows a mandrel receiving surface made in

5 accordance with the invention;

Fig. 37 shows an alternative embodiment of an apparatus constructed in accordance with the invention;

Fig. 38 is a top view of FIG. 37.;

10 Fig. 39 shows a means for deforming a stent made in accordance with the embodiment shown in FIGS. 37 and 38;

Fig. 40 is a side view of the deforming means shown in FIG. 39;

Fig. 41 shows a stent aligning and welding jig constructed in accordance with the invention;

15 Fig. 42 shows a mandrel support lever;

Fig. 43 is a front view of the jig shown in FIG. 41;

Fig. 44 is a top view of the jig shown in FIG. 43;

Fig. 45 shows the mandrel support lever of FIG. 42 disposed on the jig of FIG. 41;

20 Fig. 46 shows a mount for electropolishing a stent;

Fig. 47 shows the mount of FIG. 46 with the stent moved in a longitudinal direction;

Fig. 48 shows a rack for electropolishing a stent with material to be sacrificed disposed at the ends;

25 Fig. 49 shows a stent still attached to a metal sheet for electropolishing by attaching an electrode to the sheet; and

Fig. 50 is a side view of FIG. 49 showing the stent and the remaining portion of the sheet.

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DETAILED DESCRIPTION OF A PREFERRED EMBODIMENT

Reference is now made to Fig. 1, which illustrates the stent fabrication method of the present invention and to Figs. 2A, 2B, 2C, 3 and 4 which are useful in understanding the method of Fig. 1.

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In the stent fabrication method of the present invention, a stent designer first prepares a drawing of the desired stent pattern in a flat format (step 10).

15 Figs. 2A, 2B and 2C illustrate three exemplary stent pattern designs. The pattern of Fig. 2A has two types of sections 20 and 22. Each section 20 has two opposing periodic patterns and each section 22 has a plurality of connecting lines 24. The pattern of Fig. 2A can be formed of any size; a preferable size is to have each section 20 be between 1 and 6mm wide and each section 22 have connecting lines 24 of 1 - 6mm long. At such sizes, the pattern of Fig. 2A cannot be cut using a laser cutting system.

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The pattern of Fig. 2B is similar to that of Fig. 2A in that it also has sections 20 of opposing periodic patterns. The pattern of Fig. 2B also has connecting sections, labeled 30, which have a Z shape.

The pattern of Fig. 2C has no connecting sections. Instead, it has a series of alternating patterns, labeled 32 and 34.

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The patterns of Figs. 2A, 2B and 2C optionally also have a plurality of small protrusions 38 which are useful in

5 forming the stent, as described hereinbelow.

 Returning to Fig. 1, in step 12, the stent pattern is cut into a flat piece of metal ("sheet metal"). The metal can be any type of biocompatible material, such as stainless steel, or a material which is plated with a biocompatible material. The
10 cutting operation can be implemented in any of a number of ways, such as by etching, or by cutting with a fine cutting tool, or by cutting with a very fine laser, should one become commercially available.

 If step 12 is implemented with etching, then, the
15 process is designed to cut through the sheet metal. This process is known; however, for the purposes of completeness, it will be briefly described hereinbelow.

 The drawing of the pattern is reduced and printed onto a transparent film. Since it is desired to cut completely
20 through the metal, the drawing is printed onto two films which are joined together in a few places along their edges. The sheet metal is covered, on both sides, with a layer of photoresist and placed between the two transparent, printed films. The structure is illuminated on both sides which causes the portions of the
25 photoresist which receive the light (which are all the empty spaces in the pattern, such as spaces 26 of Fig. 2A) to change properties.

 The sheet metal is placed into acid which eats away those portions of the photoresist which changes properties. The
30 sheet metal is then placed into an etching solution which etches

5 away all material on which there is no photoresist-removing
solution which removes the photoresist, leaving the metal having
the desired stent pattern.

10 In step 14, the metal pattern is deformed so as to
cause its long sides (labeled 28 in Figs. 2A, 2B and 2C) to meet
each other. Fig. 3 illustrates the deformation process. For
cylindrical stents, the deformation process is a rolling process,
as shown.

15 If the protrusions 38 have been produced, after
deformation of the metal pattern, the protrusions 38 protrude
over the edge 28 to which they are not attached. This is
illustrated in Fig. 5A.

20 In step 16, the edges 28 are joined together by any
suitable process, such as spot welding. If the protrusions 38
were made, the protrusions 38 are joined to the opposite edge 28,
either by welding, adhesive or, as illustrated in Fig. 6, with a
nail-like element 40. Fig. 5B illustrates the connection of the
protrusion to the opposite edge 28. Since protrusion 38 is
typically designed to extend the width of one loop 39, the
pattern is approximately preserved. This is seen in Fig. 5B.

25 Alternatively, the edges 28 can be brought together and
joined in the appropriate places.

30 Fig. 4 illustrates a stent 31 formed by the process of
steps 10 - 16 for the pattern of Fig. 2A. It is noted that such
a stent has connection points 32 formed by the joining of the
points 30.

5 Finally, the stent 31 is polished to remove any excess
material not properly removed by the cutting process (step 12).
The polishing can be performed mechanically, by rubbing a
polishing stick having diamond dust on its outside inside the
stent 31. Alternatively, an electropolishing unit can be
10 utilized.

Fig. 7 shows an alternative embodiment of the invention
in which a plurality of patterns 120 are etched and cut into the
sheet metal 121 as previously discussed. Fig. 8 is an enlarged
view of one of the plurality of patterns 120 shown in Fig. 7.

15 Fig. 9 is an enlarged view of one pair 127 of the
plurality of engagement troughs 128 and 129 shown in Fig. 8.
Fig. 10 is an enlarged view of one pair 130 of the plurality of
engagement protrusions 131 and 132 shown in Fig. 8. The sheet
metal 121 and each of the patterns 120 is provided with a
20 plurality of alignment apertures 122 and 122' adapted to receive
sprockets (not shown) for precisely moving and maintaining the
precise alignment of the sheet metal 121 and the patterns 120
during the various stages of manufacturing. Each pattern 120 has
a first long side 123 and a second long side 124, a first short
25 side 125, and a second short side 126. The first long side 123
is provided with a plurality of pairs 127, 127' and 127" of
engagement troughs 128 and 129 (shown in greater detail in Fig.
9). Each pair 127, 127' and 127" of engagement troughs has a
first engagement trough 128 and a second engagement trough 129.
30 The second long side 124 is provided with a plurality of pairs

5 130, 130' and 130" of engagement protrusions (shown in greater
detail in Fig. 10). Each pair 130, 130' and 130" of engagement
protrusions is provided with a first engagement protrusion 131
and a second engagement protrusion 132. The pairs of engagement
10 protrusions 130, 130' and 130" are disposed substantially
opposite the pairs of engagement troughs 127, 127' and 127".

The engagement troughs 128 and 129 are disposed and
adapted to receive and engage the engagement protrusions 131 and
132 so that the alignment of the stent is maintained when the
pattern 120 is deformed and the flat sheet metal is rolled so
15 that the first long side 123 and the second long side 124 meet
each other to form a tube as shown in Figs. 19 and 20.

A bridge 133 of material is disposed between each pair
127, 127' and 127" of engagement troughs 128 and 129. This
bridge 133 imparts additional stability and facilitates alignment
20 during manufacturing and imparts additional strength to the welds
of the finished stent as discussed below.

After the sheet has been rolled into a tubular stent
and the engagement troughs 128 and 129 have received the
engagement protrusions 131 and 132, means (not shown) are
25 utilized to maintain the alignment and the bridge 133 is cut to
leave two substantially equal parts. The bridge 133 may be cut
in a variety of ways well known to those skilled in the art,
however, in a preferred embodiment, a laser is utilized.
Engagement trough 128 is welded to engagement protrusion 131 and
30 engagement trough 129 is welded to engagement protrusion 132 as

5 shown in Figs. 12 and 13. This may be accomplished in a variety
of ways well known to those skilled in the art, however, in a
preferred embodiment a plurality of spot welds are utilized. In
an especially preferred embodiment, about five spot welds are
used in each weld run as shown in Figs. 12 and 13. The heat
10 produced by the welding melts the cut bridge 133 material and the
material is drawn towards the engagement trough 128 or 129 to
which the material is attached and is drawn into the welded area
between the engagement trough and the engagement protrusion where
the additional bridge material becomes part of and imparts
15 additional strength to the weld. The stent may then be finished
as previously discussed.

Fig. 13 is an enlarged view of the welded area shown in
Fig. 12. In a preferred embodiment, the weld run is offset from
the point where the engagement trough and the engagement
20 protrusion contact each other. In an especially preferred
embodiment, the weld run is offset about .01 mm.

Fig. 14 is a detailed view of the pattern shown in Fig.
8. As shown in Figs. 14 and 20, Applicants' invention can also
be described as an expandable stent defining a longitudinal
25 aperture 80 having a longitudinal axis or extension 79 and a
circumferential axis or extension 105, including a plurality of
flexible connected cells 50 with each of the flexible cells 50
having a first longitudinal end 77 and a second longitudinal end
78. Each cell 50 also is provided with a first longitudinal apex
30 100 disposed at the first longitudinal end 77 and a second

5 longitudinal apex 104 disposed at the second longitudinal end 78.
Each cell 50 also includes a first member 51 having a
longitudinal component having a first end 52 and a second end 53;
a second member 54 having a longitudinal component having a first
end 55 and a second end 56; a third member 57 having a
10 longitudinal component having a first end 58 and a second end 59;
and a fourth member 60 having a longitudinal component having a
first end 61 and a second end 62. The stent also includes a
first loop 63 defining a first angle 64 disposed between the
first end 52 of the first member 51 and the first end 55 of the
15 second member 54. A second loop 65 defining a second angle 66 is
disposed between the second end 59 of the third member 57 and the
second end 62 of the fourth member 60 and is disposed generally
opposite to the first loop 63. A first flexible compensating
member or flexible link 67 having a first end 68 and a second end
20 69 is disposed between the first member 51 and the third member
57 with the first end 68 of the first flexible compensating
member or flexible link 67 communicating with the second end 53
of the first member 51 and the second end 69 of the first
flexible compensating member or flexible link 67 communicating
25 with the first end 58 of the third member 57. The first end 68
and the second end 69 are disposed a variable longitudinal
distance 70 from each other. A second flexible compensating
member 71 having a first end 72 and a second end 73 is disposed
between the second member 54 and the fourth member 60. The first
30 end 72 of the second flexible compensating member or flexible

5 link 71 communicates with the second end 56 of the second member
54 and the second end 73 of the second flexible compensating
member or flexible link 71 communicates with the first end 61 of
the fourth member 60. The first end 72 and the second end 73 are
disposed a variable longitudinal distance 74 from each other. In
10 a preferred embodiment, the first and second flexible
compensating member or flexible links 67 and 71 are arcuate. The
first and second flexible compensating member or flexible links
67 and 71 are differentially extendable or compressible when the
stent is bent in a curved direction away from the longitudinal
15 axis 79 of the aperture 80. (Shown in Fig. 20.) The first member
51, second member 54, third member 57, and fourth member 60 and
the first loop 63 and the second loop 65 and the first flexible
compensating member or flexible link 67 and the second flexible
compensating member or flexible link 71 are disposed so that as
20 the stent is expanded the distance between the first flexible
compensating member or flexible link 67 and the second flexible
compensating member or flexible link 71 increases and the
longitudinal component of the first member 51, second member 54,
third member 57 and fourth member 60 decreases while the first
25 loop 63 and the second loop 65 remain generally opposite to one
another, the ends 68 and 69 of the first flexible compensating
member or flexible link 67 and the ends 72 and 73 of the second
flexible compensating member or flexible link 71 open so as to
increase the variable longitudinal distance 70 between the first
30 end 68 and the second end 69 of the first flexible compensating

member or flexible link 67 and so as to increase the variable longitudinal distance 74 between the first end 72 and the second end 73 of the second flexible compensating member or flexible link 71. This compensates for the decreasing of the longitudinal component of the first member 51, second member 54, third member 57, and fourth member 60 and substantially lessens the foreshortening of the stent upon its expansion. Upon expansion, the first flexible compensating member 67 and the second flexible compensating member 71 impart support to the lumen being treated.

Fig. 15 shows the dimensions of an especially preferred embodiment of this invention. The deflection points, i.e., the first and second loops 63 and 65 and the first and second compensating members 67 and 71, are made wider than the first, second, third, and fourth members 51, 54, 57 and 60 so that the force of the deflection is distributed over a wider area upon the expansion of the stent. The deflection points can be made wider than the first, second, third and fourth members in differing amounts so that the deflection will occur in the narrower areas first due to the decreased resistance. In a preferred embodiment, the first and second compensating members are wider than the first, second, third and fourth members and the first and second loops are wider than the first and second compensating members. One of the advantages of sizing the first and second loops so that they are wider than the first and second compensating members is that the stent will substantially compensate for foreshortening as the stent is expanded. In the

embodiment shown in Fig. 15, the first, second, third and fourth members 51, 54, 57 and 60 have a width of about 0.1 mm. The first and second loops 63 and 65 have a width of about 0.14 mm. The first and second compensating members 67 and 71 are provided with a thickened portion 75 and 76 having a width of about 0.12 mm. Thus, in this especially preferred embodiment, the first and second loops have a width that is about 40% greater and the first and second compensating members have a width that is about 20% greater than the width of the first, second, third and fourth members.

Figs. 16 through 20 show details of a stent constructed in accordance with this invention.

Yet another advantage of Applicant's invention is shown in Figs. 21 to 24. For the sake of clarity, the dimensions and the degree of displacement of the components of the stents shown in Figs. 21 to 24 has been intentionally exaggerated.

Fig. 21 is a cross-sectional front view taken along line A-A of the unexpanded stent made in accordance with applicants invention shown in Fig. 20. The unexpanded stent 200 of Fig. 21 is shown disposed in the lumen 202 of a blood vessel 201 prior to expansion. As previously discussed, this stent is made by first cutting the stent pattern into a flat piece of sheet metal and then rolling the sheet metal into a tube to form the tubular stent. As shown in Fig. 21 after rolling, the first and second flexible compensating members 67 and 71 of the unexpanded stent tend to "flare out" in a direction away from the

5 longitudinal axis or lumen of the stent. Thus, the flexible
compensating members 67 and 71 define outer diameters which are
larger than the outer diameters defined by the remaining portions
of the stent. Fig. 22 shows the stent of Fig. 21 after it has
been expanded in the lumen and against the internal wall of the
10 blood vessel. As shown in Fig. 22, upon expansion of the
unexpanded stent toward the wall of the blood vessels, the walls
of the blood vessel imparts a mechanical force to the first and
second flexible compensating members 67 and 71 and the
compensating members move toward the longitudinal axis or lumen
15 of the stent until they are substantially in registry with the
remaining portion of the stent. Thus, the lumen of the expanded
stent is substantially circular when viewed in cross section with
substantially no portion of the expanded stent projecting into
the lumen or towards the longitudinal axis of the expanded stent.

20 Fig. 23 is similar to Fig. 21 except that the pattern
has been cut into a tubular member using conventional methods of
making stents. As shown in Fig. 23, the flexible compensating
members do not flare out away from the longitudinal axis of the
unexpanded stent 203. Upon the expansion of the stent shown in
25 Fig. 23 toward the walls of the blood vessel 201, the flexible
compensating members 67' and 71' tend to "flare in" and project
into the lumen 204 of the expanded stent 203.

Fig. 24 shows the stent 203 of Fig. 23 after it has
been expanded in a lumen 204 of a blood vessel 201. The flexible
30 compensating members 67' and 71' are not in registry with the

5 remaining portions of the stent and define a diameter smaller than the diameter of remaining portions of the stent. These projections into the lumen of the stent create turbulence in a fluid flowing through the longitudinal axis of the expanded stent and could result in clot formation.

10 Applicant's invention is also directed to an apparatus for fabricating a stent, comprising a platform, a mandrel, and means for deforming a sheet of metal around the mandrel.

The platform is adapted to receive a flat sheet of metal to be formed into a stent. In a preferred embodiment, the flat sheet of metal is provided with a first end, a second end defining a longitudinal axis, a first major surface, a second major surface, a first long side, a second long side, with the first and said second long sides substantially parallel to the longitudinal axis of the sheet. The mandrel has a substantially cylindrical external surface and a first end and a second end defining a longitudinal axis. The mandrel is sized to have a cross-sectional diameter substantially equal to or less than the internal diameter of a stent to be fabricated. A means for securing the mandrel against a major surface of the flat sheet of metal is provided. A means for deforming the flat sheet of metal around the external surface of the mandrel is also provided to deform the flat sheet of metal into a substantially tubular shape that substantially conforms to the external surface of the mandrel. In a preferred embodiment, the means for deforming the sheet is adapted so that the first long side and the second long

5 side remain substantially parallel to each other when the flat sheet of metal is deformed into a tubular shape. A means, e.g., a welding apparatus, laser, adhesive, or screw secures the first long side of the sheet to the second long side of the sheet.

10 In operation of a preferred embodiment a plurality of stent patterns are cut or etched into a flat piece of metal. Each of the patterns has a first long side and a second long side, with the first long side provided with a plurality of pairs of engagement points and second long side provided with a plurality of pairs of engagement points. The plurality of pairs
15 of engagement points are disposed substantially opposite each other and are sized and disposed to communicate when the pattern is deformed and rolled into a tubular shape. Each pair of the first long side engagement points is provided with a bridge disposed between each first long side engagement point comprising
20 the pair, the bridge having a width that is less than the width of the other portions of the stent.

A mandrel is disposed between the first and second long sides of the sheet. The mandrel has a substantially cylindrical external surface and a longitudinal axis substantially parallel
25 to the first long side and the second long sides. The pattern is deformed into a tubular shape so that the first long side pairs of engagement points contact the second long side pairs of engagement points.

The bridge is cut and each of the engagement points is
30 attached to the engagement point with which it is in contact to

5 form the expandable stent.

Figs. 25 to 28 show a preferred embodiment of an apparatus for fabricating and a stent constructed in accordance with Applicants' invention. The apparatus comprises a laser housing 300, a laser 301, a movable table __, and a plurality of stent folders 303 disposed on the table. The laser 301 is disposed within and selectively movable within the housing 300. The movable table 302 has a first end 304 and a second end 305 and is adapted for selective movement into and out of the laser housing 300. The table 302 is adapted so that when the first end 304 of the table 302 is disposed within the laser housing 300 the second end of the table 305 is disposed outside of said housing 300 and when said second end 305 of the table 302 is disposed within the laser housing 300 the first end 304 of the table 302 is disposed outside of the laser housing 300.

20 A plurality of stent folders 303 is disposed at the first end 304 of the table and a plurality of stent folders 303 is disposed at the second end 305 of the table 302. As shown in FIGS. 26 and 27, each of said stent folders comprises:

25 A base 306 having a platform 307 adapted to receive a flat sheet of metal 120 to be formed into a stent. The flat sheet of metal 120 has a longitudinal axis, a first major surface, a second major surface, a first long side, and a second long side, with the first and the second long sides substantially parallel to the longitudinal axis. The sheet is also provided with a plurality of alignment of apertures.

5 A plurality of alignment pins 308 project from each of the platforms. The pins 308 are sized to engage the alignment apertures 122 and align the sheet on the platform 307.

10 A mandrel 309 is provided having a substantially cylindrical external surface 310 and having a first end 311, a second end 312, and a longitudinal axis 313 as shown in FIGS. 35. The mandrel 309 is sized to have a cross-sectional diameter substantially equal to or less than the internal diameter of the stent to be fabricated. The
15 platform 307 is provided with a first concave recess 314 adapted to receive the first end 311 of the mandrel and a second concave recess adapted to receive the second end 312 of the mandrel 309 as shown in FIG. 36.

20 A hingedly connected arm 316 is adapted for movement in a first direction toward the platform 307 and in a second direction away from the platform 307 for securing the mandrel 309 against a major surface of said flat sheet of metal when it is disposed on the platform;

25 Each stent folder 303 is provided with a first deforming blade 316 provided with a first deforming blade tip 316; a second deforming blade 317 provided with a second deforming blade tip 317; a third deforming blade 318 provided with a third deforming blade tip 318; a fourth deforming blade 319 provided with a fourth deforming blade
30 tip 319; a fifth deforming blade 320 provided with a fifth

5 deforming blade tip 320; and a sixth deforming blade 321
provided with a sixth deforming blade tip 321. The blades
are disposed around the external surface 310 of the mandrel
309 and are adapted to deform the flat sheet of metal
against the external surface 310 of the mandrel 309 so that
10 the flat sheet of metal is deformed into a substantially
tubular shape substantially conforming to the external
surface 310 of the mandrel 309. The deforming blades are
disposed between the first end and the second end 312 of the
mandrel 309. Each of the deforming blades is adapted for
15 independent and selective movement in a first direction
toward the mandrel 309 and a second direction away from the
mandrel so as to selectively impinge the deforming blade
tips 316, 317, 318, 319, 320, and 321 against the mandrel or
against a portion of the sheet disposed between the mandrel
20 and each of the deforming blade tips. Each of the deforming
blades is also adapted so that the first long side and the
second long side of the sheet remain substantially parallel
to each other when the sheet is deformed into the tubular
shape. The third and the sixth deforming blade tips 318 and
25 321 are provided with a plurality of scalloped laser
apertures 322 which are sized and disposed to permit the
third and the sixth deforming blade tips to secure the first
long side and the second long side against the external
surface of the mandrel while providing the laser 301 access
30 to predetermined portions of the first long side and the

5 second long side in order to weld the first long side to the second long side.

 A first motor 323 is connected to the first deforming blade; a second motor 324 is connected to the second deforming blade; a third motor 325 is connected to the third deforming blade; a fourth motor 326 is connected to the
10 fourth deforming blade; a fifth motor 327 is connected to the fifth deforming blade; and a sixth motor 328 is connected to the sixth deforming blade. Each of the motors is adapted for selectively moving each of the deforming
15 blades to which it is connected in a first direction toward the mandrel and in a second direction away from the mandrel.

 A computer 329 controls the sequence which the first end of the table and the second end of the table are disposed within the laser housing; the sequence and degree
20 to which each of the deforming blade tips impinges upon the mandrel or a portion of the sheet disposed between the mandrel and each of the deforming blade tips; and the sequence, pattern, location, and amount of energy the laser
25 applies to each of the first and second long sides of each of the sheets disposed on each of the plurality of stent folders.

 Each of the blade deforming tips has a length substantially equal to the first and the second long sides of the flat sheet of metal and in a preferred forming blade tips are
30 concave as shown in FIG. 27.

5 In an especially preferred embodiment, as shown in FIG.
27 the third deforming blade tip is substantially identical to
the sixth deforming blade tip; the second deforming blade tip is
substantially identical to the fifth deforming blade tip; and the
first deforming blade tip is substantially identical to the
10 fourth deforming blade tip.

 In operation, the apparatus shown in FIGS. 25 to 27 and
discussed in detail above is constructed. A plurality of stent
patterns is cut into a flat piece of metal, each of the patterns
having a first major surface and a second major surface, a first
15 long side and a second long side. The first long side and the
second long sides are provided with a plurality of pairs of
engagement points 329, 330, 331, and 332, as shown in FIGS. 28
and 29, disposed substantially opposite each other and sized and
disposed to communicate when the pattern is deformed and rolled
20 into a tubular shape. Each pair of the first long side
engagement points is provided with a bridge 333 disposed between
each first long side engagement point 329 and 330 comprising the
pair. Preferably, the bridge 333 has a width that is less than
the width of the other portions of the stent. The sheet is also
25 provided with a plurality of alignment ~~221~~ apertures sized and
disposed to engage the alignment pins 308 on the base 306.

 The sheet is disposed on the base so that the first
major surface of the sheet is in contact with the base.

 A mandrel 309 having a substantially cylindrical
30 external surface 310 and a longitudinal axis 313 is disposed

5 against the second major surface of the sheet between the first
long side and the second long side of the sheet with the
longitudinal axis substantially parallel to the first long side
and the second long side, as shown in FIG 30A..

10 The pattern is deformed into a tubular shape so that
the first long side pairs of engagement points contact the second
long side pairs of engagement points, as shown in FIG. 29. The
deforming step comprises the steps of:

15 a) actuating the sixth deforming blade motor so that
the sixth deforming blade motor moves the sixth
deforming blade in the first direction in an amount
sufficient for the sixth deforming blade tip to contact
the external surface of the mandrel so as to secure
said mandrel against said sheet, as shown in FIG. 30B.

20 The first deforming blade motor is activated so
that the first blade deforming motor moves the first
deforming blade in the first direction in an amount
sufficient for the first blade deforming tip to contact
the first major surface of the sheet and deform the
sheet against the external surface of the mandrel, as
25 shown in FIG. 30C.

30 The second deforming blade motor is then activated
so that the second deforming blade motor moves the
second deforming blade in the first direction in an
amount sufficient for the second deforming blade tip to
contact the first major surface of the sheet and deform

5 the sheet against the external surface of the mandrel,
as shown in FIG. 30D.

10 The third deforming blade motor is then activated
so that the third deforming blade motor moves the
second deforming blade in the first direction in an
amount sufficient for the third deforming blade tip to
contact the first major surface of the sheet and deform
the sheet against the external surface of the mandrel
while actuating the sixth deforming blade motor so that
the sixth deforming blade moves in the second direction
15 away from said mandrel, as shown in FIG. 30E.

20 The fourth deforming blade motor is then activated
so that the fourth deforming blade motor moves the
fourth deforming blade tip in the first direction in an
amount sufficient for the fourth deforming blade tip to
contact the first major surface of the sheet and deform
the sheet against the external surface of the mandrel,
as shown in FIG. 30F.

25 The fifth deforming blade motor is then activated
so that the fifth deforming blade motor moves the fifth
deforming blade in the first direction in an amount
sufficient for the fifth deforming blade tip to contact
the first major surface of the sheet and deform the
sheet against the external surface of the mandrel, as
shown in FIG. 30G.

30 The sixth deforming blade motor is then activated

5 so that the sixth deforming blade motor moves the sixth
deforming blade in said first direction in an amount
sufficient for said sixth deforming blade tip to
contact the first major surface of the sheet and deform
the sheet against the external surface of the mandrel,
10 as shown in Fig. 30H.

The third and sixth deforming blade motors are
then simultaneously activated so that the third and
sixth deforming blade motors move the third and sixth
deforming blades in the first direction in an amount
15 sufficient for the third and sixth deforming blade tips
to contact the first major surface of the sheet and
deform the sheet against the external surface of the
mandrel.

The laser is used to cut the bridge. The laser is then used
20 to weld each of the engagement points to the engagement point
with which it is in contact to form the expandable stent.

In a preferred embodiment, the bridge has a width that is
about 25% to about 50% of the width of the other portions of said
stent and in an especially prepared embodiment the bridge has a
25 width of about 40 microns.

The engagement points, as shown in FIGS. 28 and 29 are sized
and adapted to move in an amount sufficient so as to reduce the
likelihood of material stress occurring during welding heating
and cooling cycles.

30 A V-shaped notch 334 may be formed between the first long

5 side and the second long side when the stent is deformed to
provide for a stronger weld, as shown in FIG. 31. In addition,
as shown in FIG. 31 a gap 335 may be provided between the
engagement points and the external surface of the mandrel 309
during the deforming step. This gap 335 provides a greater area
10 for weld material, thus, strengthening the weld and reducing heat
dissipation through the mandrel during welding, thus, reducing
the amount of energy that must be put into the weld.

Additional weld fill material 336 may be provided on the
side of each of the engagement points substantially opposite the
15 bridge, as shown in Figs. 33 and 34. The weld fill material is
sized and disposed so as to permit the additional weld fill
material to be drawn into the weld point during welding.

After the stent has been deformed and the engagement points
have contacted each other, the bridge is cut using the laser.
20 The first side and long sides are then connected using the laser
to form a weld that is preferably wider than the other portions
of the stent. In an especially preferred embodiment, the weld is
about 20% wider than the other portions of the stent and has a
width of about 140 microns. The weld is preferably run from
25 outside-to-in. A plurality of welding runs is preferably used
and, in an especially preferred embodiment two weld-runs are
utilized. The weld-run may be offset from the point where the
engagement points contact each other and in a preferred
embodiment is offset about .01 mm from the point where said
30 engagement points contact each other.

5 The weld may be a spot weld, a plurality of spot welds, and
in a preferred embodiment, the weld comprises 5 spot welds.

 In a preferred embodiment, the pattern is cut into the sheet
using multiple-up-etching and comprises the step of inspecting
both sides of the sheet after etching and before the sheet is
10 disposed on the base. In an especially prepared embodiment the
inspection step is carried out using an automated optical
inspection apparatus.

 In an especially preferred embodiment, the stent patterns
are adapted so that upon the expansion of the stent against the
15 internal wall of a vessel substantially no portion of the stent
projects into the longitudinal lumen of the stent. The stent may
be finished by electropolishing.

 FIGS. 37 to 40 show another embodiment of an apparatus for
fabricating a stent constructed in accordance with the invention.

20 A base 401 is provided with a sheet receiving area 402 and
is adapted to receive a flat sheet of metal to be formed into a
stent. The sheet receiving area 402 is also provided with a
mandrel receiving groove 409. In a preferred embodiment, the
flat piece of metal has a longitudinal axis, a first major
25 surface, a second major surface, a first long side, and a second
long side, with the first and the second long sides substantially
parallel to the longitudinal axis. An arm 403 having a first end
404 and a second end 405 is provided.

 The first end 404 of the arm is adapted to selectively
30 retain a mandrel 406 having a substantially cylindrical external

5 surface. The second end of the arm 405 is hingedly connected to
the base 405 and is adapted for movement in a first direction
toward the base 401 and in a second direction away from the base
401 to secure the mandrel against a major surface of the flat
sheet of metal. The mandrel 406 is sized to have a cross-
10 sectional diameter substantially equal to or less than the
internal cross-sectional diameter of the stent to be fabricated.

A means 407 is provided for deforming the flat piece of
metal against and around the external surface of the mandrel so
that the flat sheet of metal is deformed into a substantially
15 tubular shape conforming to the external surface of the mandrel
with the first long side and the second long side substantially
parallel to each other. FIG. 39 shows one embodiment wherein the
means 407 for deforming is a member provided with a deforming tip
408 having a length substantially equal to the length of the
20 first and second long sides of the sheet metal. In a preferred
embodiment, the deforming tip is concave, as shown in FIG. 40.

In operation, a sheet is placed on the sheet receiving area
402. A mandrel 406 is disposed in the first end 404 of the arm
403 and the arm 403 is moved in the first direction so that the
25 mandrel is in contact with the sheet. The deforming means is
then used to deform the sheet around the mandrel a previously
discussed. The arm is then moved in the second direction and the
mandrel with the sheet wrapped around it is removed from the
first end 404 of the arm 403. The first and second long sides
30 are then connected as previously discussed to form the stent. In

5 a preferred embodiment, the mandrel with the sheet wrapped around it is transferred to the stent aligning and welding jig shown in FIGS. 41 to 45.

10 The stent aligning and welding jig shown in FIGS. 41 to 45 comprises a base 500 having a first end and a second end provided with a first wall 501 having a first end and a second end and a first major surface 502 and a second major surface 503 and a second wall 504 having a first end and a second end and a first major surface 505 and a second major surface 506. The second major surface 503 of the first wall 501 and the first major surface 505 of the second wall 504 define a longitudinal U-shaped channel 507 having a longitudinal axis in the base 500. The first wall 501 is provided with a plurality of slots 508 defining a plurality of first clamping portions 509 having a top end 511 and a bottom end 512 and a first major surface 502 and a second major surface 503. Each of the first clamping portions 509 is provided with a first concave channel 510 disposed at the top end 511 of the second major surface 503 of the first clamping portion 509 and a second concave channel 513 disposed at the bottom end 512 of the second major surface 503 of the first clamping portion 509. The first and the second concave channels 510 and 513 are substantially parallel to the longitudinal axis of the U-shaped channel. The ~~first wall 502~~ ^{second major surface 503} of each of the plurality of first clamping portions is also provided with a compensation slit 514 disposed between the first concave channel 510 and the second concave channel 513 substantially parallel to the longitudinal

5 axis of the U-shaped channel 507.

A plurality of second clamping portions 515 is disposed in the U-shaped channel 507 between the second major surface 503 of the first wall 501 and the first major surface 505 of the second wall 504. Each of the second clamping portions 515 is disposed
10 in registry with one of the first clamping portions 509. Each of the second clamping portions 515 has a top end 516, a bottom end 517, a first major surface 518, a second major surface 519, a first minor surface disposed at the top end, a second minor surface disposed at the bottom end, a third minor surface
15 disposed between the top end and the bottom end 520, and a fourth minor surface disposed opposite the third minor surface between the top end 516 and the bottom end 517. Each of the second clamping portions 515 is provided with a first concave channel 521 disposed at the top end 516 of the first major surface 518 of
20 the second clamping portion 515 and a second concave channel ~~522~~ 513⁰ disposed at the bottom end 517 of the first major surface 518 of the second clamping portion 515. The first and the second concave channels 521 and ~~522~~ 513⁰ are substantially parallel to the longitudinal axis of the U-shaped channel.

25 A biasing means 523 is disposed between the first major surface 505 of the second wall 504 and the second major surface 503 of each of the of second clamping portions 509 for biasing the first major surface of each of the second clamping portions against the second major surface of each of the first clamping
30 portions which are in registry with each other.

5 A first mandrel support lever positioning pin 524 projects from the third minor surface 520 and a second mandrel support lever positioning pin 521 projects from the fourth minor surface of each of the second clamping portions 515. The mandrel support lever positioning pins 520^u and 521 are substantially parallel to
10 the longitudinal axis of the U-shaped channel.

A biasing control means 522 selectively controls the distance between the second major surface of each of the first clamping portions 509 and the first major surface 518 of each of the second clamping portions 515.

15 A retaining mandrel 523⁵⁵⁵ is disposed in the second concave channel 513 of the first wall and the second concave channel 522⁵⁰¹ 513' in each of the second clamping portions 515.

A mandrel support lever, 524⁵³⁴, as shown in FIG. 42, supports the stent during the alignment of the first long side of the sheet with the second long side of the sheet. The lever 524 is provided with a first mandrel support notch 525 for supporting the first end of the mandrel and a second mandrel support notch 526 for supporting the second end of the mandrel. A first mandrel support lever positioning pin engagement surface 527
20 engages the first mandrel support lever positioning pin 524 and a second mandrel support lever positioning pin engagement surface 528 engages the second mandrel support lever positioning pin when the mandrel support lever is disposed on the second wall.

25 It will be appreciated that various elastic materials well known to those skilled in the art as suitable for this purpose
30

5 may be utilized, e.g., a spring, however, in an especially preferred embodiment, the elastic material is rubber.

10 In a preferred embodiment the biasing control means 522 is a threaded screw disposed in each of the first clamping portions 509 with each of the screws 522 communicating with the first major surface 502 and the second major surface 503 of each of the first clamping portions 509. The screws 522 are selectively movable in a direction toward and away from the first major surface 518 of the second clamping portion 515 to selectively move the second clamping portion 515 in a direction toward and away from the first clamping portions 501 to selectively vary the distance between the second major surface 503 of each of the first clamping portions 509 and the first major surface 518 of each of the second clamping portions 515.

20 In operation, the mandrel with the sheet wrapped around it is secured in the first concave channels 510 and 521. The biasing control means 522, e.g., a screw, is adjusted to secure the mandrel in the first concave channels while permitting the first and second long sides of the sheet to be adjusted so that the contact points are aligned as desired. In a preferred embodiment, the mandrel support lever shown in FIG. 42, is utilized to support the mandrel during the alignment operation. A shown in FIG. 45, the first mandrel support notch supports the first end of the mandrel and the second mandrel support notch supports the second end of the mandrel. The first mandrel support lever positioning pin surface engages the first mandrel

30

5 support lever positioning pin and the second mandrel support
lever positioning pin surface engages the second mandrel support
positioning pin so as to align the mandrel support lever when it
is supporting the mandrel.

FIGS. 46 to 48 show a jig for electropolishing a tubular
10 stent, comprising a rack having a first end and a second end and
provided with a plurality of stent electropolishing mounts. Each
of the mounts is provided with a base and an electrically
conductive first member having a first end connected to the base
and a second end adapted to selectively contact the external
15 surface of the tubular stent to be electropolished without
damaging its external surface. The mounts are also provided with
an electrically non-conductive second member having a first end
connected to the base and a second end adapted to be selectively
disposed within the longitudinal bore of the stent without
20 damaging the surface defining the longitudinal bore. The first
member and the second member are also adapted so as to bias the
second end of the second member towards the second end of said
first member in an amount sufficient to secure said stent between
said first and said second members. The advantage of a mount
25 constructed in accordance with applicants' invention is that the
electrically conductive member controls the external surface of
the stent. This reduces the likelihood of undulations and
erosion lines occurring on the surface defining the longitudinal
bore. These erosion lines frequently occur in stents
30 electropolished utilizing conventional mounts which place the

5 electrically conductive member against the surface defining the longitudinal bore. Electropolishing a stent with Applicants' mount reduces the likelihood that the longitudinal lumen of the stent will have an irregular surface which could result in turbulent fluid flow which could result in thrombosis or platelet
10 aggregation.

In a preferred electropolishing method a stent is placed on a rack constructed as previously discussed. The method comprises immersing the stent in an electropolishing bath and applying electrical current to the first member for a predetermined period
15 of time; and changing the point where the second end of the first member contacts the external surface of the stent prior to the expiration of the predetermined period of time. Changing the point of contact minimizes the concentration of undulations or erosion lines at any given point on the stent near the point of
20 contact of the electrically conductive member. The point of contact may be changed by rotating the stent. In an especially preferred embodiment, the point of contact is changed by varying the distance between the stent and the base by longitudinally moving the stent toward or away from the base as shown in FIGS.
25 46 and 47. The point of contact is changed at about the midpoint of the predetermined period of time. In an especially preferred embodiment, the treatment is interrupted before the expiration of the predetermined time, the effect of the electropolishing prior to the interruption step is evaluated, and the remaining period
30 of the predetermined time is adjusted to compensate for any

5 variations in the amount of material actually removed prior to the interruption step. The treatment may be interrupted at any time, however, interruption at about the midpoint of the predetermined period of time is preferred.

10 Pieces of sacrificial material may be added at the first end and the second end of the rack to compensate for the additional material normally removed from stents disposed at the first end and the second end of the rack as shown in FIG 48. The material is selected and added in an amount sufficient to substantially equalize the amount of additional material normally removed from
15 the stents disposed first and second ends of the rack.

In yet another preferred method of electropolishing a stent, the stent is manufactured as previously discussed however, when deforming the pattern into a tubular shape so that said first long side pairs of engagement points contact the second long side
20 pairs of engagement points, a portion of the stent is allowed to remain attached to the sheet of metal, as shown in FIGS. 49 and 50. The bridge is then cut, the engagement points are connected to form the stent, the stent is electropolished by connecting an electrode to the sheet, and the stent is then removed from the
25 sheet. This reduces the likelihood of damage to the stent because the sheet to which the stent is attached is disposable. This method also provides an additional advantage because the disposable sheet to which the stent is attached acts as sacrificial material as previously discussed.

30 FIGS. 33 and 34 show another embodiment of a sheet for

5 fabricating a stent in accordance with the invention. A flat
piece of sheet metal is provided with a plurality of stent
patterns, each of said patterns having a first long side and a
second long side that may be provided with alignment apertures as
previously discussed. The first long side is provided with a
10 plurality of pairs of engagement points, and the second long side
is provided with a plurality of pairs of engagement points
disposed substantially opposite each other as shown in FIGS. 33
and 34. The engagement points are sized and disposed to
communicate when the pattern is deformed and rolled into a
15 tubular shape. Each pair of the first long side engagement
points is provided with a bridge disposed between each first long
side engagement point comprising the pair. In a preferred
embodiment, the bridge has a width that is less than the width of
the other portions of the stent and preferably has a width that
20 is about 25% to about 50% of the width of the other portions of
the stent. In an especially preferred embodiment, the bridge has
a width of about 40 microns. The engagement points are sized and
adapted to move in an amount sufficient so as to reduce the
likelihood of material stress occurring during welding heating
25 and cooling cycles. The sheet may be provided with additional
weld fill material 336 on the side of each of the engagement
points substantially opposite the bridge 333. The weld fill
material is sized and disposed so as to permit the additional
weld fill material to be drawn into the weld point during
30 welding. The stent patterns are adapted so that upon expansion

5 of the stent against the internal wall of a vessel substantially
no portion of the stent protrudes into the longitudinal lumen of
the stent.

When the stent sheet for making a stent shown in FIGS. 28,
29, and 33 and 34 are made into a stent by cutting the bridges
10 and welding the connecting points, the resulting stent comprises
a stent having a longitudinal lumen comprising: a first long
side and a second long side, with the first long side provided
with a plurality of pairs of engagement points, and the second
long side provided with a plurality of pairs of engagement
15 points, with the plurality of pairs of first long side engagement
points and the plurality of pairs of second long side engagement
points disposed substantially opposite each other and connected
to each other via a weld, that is wider than the other portions
of the stent. In a preferred embodiment, the stent may be
20 provided with a weld that is about 20% wider than the other
portions of the stent. In a preferred embodiment, the weld has a
width of about 140 microns. The weld may be comprised of a
plurality of weld runs, and in a preferred embodiment, the weld
is comprised of two weld runs. The weld may be a spot weld, a
25 plurality of spot welds, and in an especially preferred
embodiment, comprises 5 spot welds. The patterns of the stent
may be adapted so that upon the expansion of the stent against
the internal wall of a vessel substantially no portion of the
stent protrudes into the longitudinal lumen of the stent.

30 It will be appreciated by persons skilled in the art

5 that the present invention is not limited to what has been particularly shown and described hereinabove. Rather the scope of the present invention is defined only by the claims which follow.